

PRELIMINARY AMENDMENT AND RCE

**Amendments to the Claims**

Please cancel claims 88, 89 and 111 without prejudice or disclaimer. Please amend claims 67, 85 and 99-102 as set forth below. The listing of claims below will replace all prior versions and listings of claims in the application.

**Listing of Claims:**

Claims 1-66. (cancelled)

67. (currently amended) A method of treating chronic sinusitis, comprising the step of:

nasally administering a pharmaceutical composition as an aerosol to a mammal diagnosed or suspected of having chronic sinusitis, wherein:

the composition comprises betamethasone; and  
a surfactant, wherein:

the composition is formulated for nasal administration as an aerosol; and

has a surface tension effective for deposition, penetration or retention of the composition in the nasal sinuses[.]  
effecting deposition, penetration or retention of the composition in the nasal sinuses to thereby treat chronic sinusitis.

68. (previously presented) The method of claim 67, wherein the composition is administered via a nebulizer having a nasal adapter.

69. (previously presented) The method of claim 68, wherein the nebulizer is connected to a compressor.

Claims 70-72 (canceled)

73. (previously presented) The method of claim 67, wherein the surfactant is selected from the group consisting of polyethylene glycol, sodium lauryl sulfate, sorbitan esters, polysorbates, tyloxapol or benzalkonium chloride.

74. (previously presented) The method of claim 67, wherein the pharmaceutical composition further comprises a second agent, wherein the second agent is selected from the group consisting of an anti-histamine, a mast cell stabilizer, a non-antibiotic anti-microbial agent, an anti-leukotriene, an anti-

viral, an antiseptic, a non-steroidal anti-inflammatory, a combination of at least two antibiotics, an agent for treating nasal polyps, an anticholinergic agent and combinations thereof.

75. (previously presented) The method of claim 74, wherein the second agent is an anti-histamine.

76. (previously presented) The method of claim 75, wherein the wherein the anti-histamine is selected from the group consisting of ethanolamine, ethylenediamine, alkylamine, phenothiazine, piperazine, cyproheptidine, azatadine, diphenylpyraline, ketotifen, terfenadine, fexofenadine, asternizole, and phenindamine.

77. (previously presented) The method of claim 76, wherein the ethanolamine is selected from the group consisting of diphenhydramine, carbinoxamine, clemastine, phenytoloxamine, doxylamine, dimenhydrinate, and bromodiphenhydramine hydrochloride.

78. (previously presented) The method of claim 74, wherein the second agent is a mast cell stabilizer.

79. (previously presented) The method of claim 78, wherein the mast cell stabilizer is selected from the group consisting of cromolyn or nedocromil sodium.

80. (previously presented) The method of claim 74, wherein the second agent is a non-antibiotic anti-microbial agent.

81. (previously presented) The method of claim 80, wherein the non-antibiotic anti-microbial agent is taurolidine.

82. (previously presented) The method of claim 74, wherein the second agent is an anti-leukotriene.

83. (previously presented) The method of claim 82, wherein the anti-leukotriene is selected from the group consisting of zafirlukast, montelukast, pranlukast, iralukast, and pobilukast.

84. (previously presented) The method of claim 74, wherein the second agent is a non-steroidal anti-inflammatory.

85. (currently amended) The [[composition]] method of claim 84, wherein the non-steroidal anti-inflammatory is selected from the group consisting of fenoprofen, flurbiprofen, ibuprofen, ketoprofen, naproxen, oxaprozin, diclofenac, etodolac, indomethacin, ketorolac, nabumetone, sulindac, tolmetin, meclofenamate, mefenamic acid, piroxicam and suprofen.

86. (cancelled)

87. (previously presented) The method of claim 67, wherein the surfactant is a polysorbate.

88. (Cancelled herein)

89. (Cancelled herein)

90. (previously presented) The method of claim 67, wherein the surface tension is about 30 to about 50 dynes/cm.

91. (previously presented) The method of claim 67, wherein the composition is formulated for administration via a nebulizer.

92. (previously presented) The method of claim 67, wherein the composition has an osmolality of about 150 mOsm/kg to about 880 mOsm/kg.

93. (previously presented) The method of claim 67, wherein the composition has an osmolality of about 300 mOsm/kg to about 880 mOsm/kg.

94. (previously presented) The method of claim 67, wherein the composition has an osmolality of about 400 mOsm/kg to about 700 mOsm/kg.

95. (previously presented) The method of claim 67, wherein the composition has an osmolality of about 500 mOsm/kg to about 600 mOsm/kg.

96. (previously presented) The method of claim 67, wherein the surfactant has a hydrophile-lipophile-balance (HLB) of between about 1.8 to about 8.6.

97. (previously presented) The method of claim 67, wherein the surfactant has a hydrophile-lipophile-balance (HLB) of between about 9.6 to about 16.7.

98. (previously presented) The method of claim 67, wherein the composition has a pH of about 3.0 to about 8.5.

99. (Currently Amended) The method of claim 67, wherein the composition is an aerosol that comprises particles in the size range of about 1.0 to about 4.0  $\mu\text{m}$  in diameter.

100. (Currently Amended) The method of claim 67, wherein the composition is an aerosol that comprises particles in the size range of about 0.5 to about 5.0  $\mu\text{m}$  in diameter.

101. (Currently Amended) The method of claim 67, wherein the composition is an aerosol that comprises particles in the size range of about 2.0 to about 3.5  $\mu\text{m}$  in diameter.

102. (Currently Amended) The method of claim 67, wherein the composition is an aerosol that comprises less than about 20% total particles having a diameter of about 5  $\mu\text{m}$ .

103. (previously presented) The method of claim 67, wherein the composition has an NaCl equivalency of about 1.1% NaCl to about 1.8% NaCl.

104. (previously presented) The method of claim 67, wherein the composition has an NaCl equivalency of about 1.3% NaCl to about 1.7% NaCl.

105. (previously presented) The method of claim 67, wherein the pharmaceutical composition is administered to the patient 1-3 times a day for a total of 14-21 days.

106. (previously presented) The method of claim 68, wherein the nebulizer delivers a majority of aerosolized particles in the size range of about 3.0 to about 3.5  $\mu\text{m}$  in diameter.

107. (previously presented) The method of claim 68, wherein the nebulizer delivers a majority of aerosolized particles in the size range of about 1.0 to about 4.0  $\mu\text{m}$  in diameter.

108. (previously presented) The method of claim 68, wherein the nebulizer delivers a majority of aerosolized particles in the size range of about 0.5 to about 5.0  $\mu\text{m}$  in diameter.

109. (previously presented) The method of claim 68, wherein the nebulizer delivers a majority of aerosolized particles in the size range of about 2.0 to about 3.5  $\mu\text{m}$  in diameter.

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110. (previously presented) The method of claim 68, wherein the maximum number of particles delivered by the nebulizer over about 5.0 microns is less than 20% of the total particles.

111. (Cancelled herein)

112. (previously presented) The method of claim 74, wherein the second agent is a combination of at least two antibiotics.

113. (previously presented) The method of claim 112, wherein the at least two antibiotics are selected from the group consisting of penicillins, cephalosporins, macrolides, ketolides, sulfonamides, quinolones, aminoglycosides, beta lactam antibiotics, and linezolid.